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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/562,393	04/25/2006	Istvan Gacsalyi	23493	8071

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EXAMINER	
KANTAMNENI, SHOBHA	
ART UNIT	PAPER NUMBER
1617	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/562,393	GACSALYI ET AL.	
	Examiner	Art Unit	
	Shobha Kantamneni	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *NONE* is/are allowed.

6)☒ Claim(s) *1-22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *01/30/2009*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This application was filed on 04/25/2006, and is a national stage entry of PCT/HU04/00062 filed on 06/22/2004. Claims 1-22 are pending.

Specification

The disclosure is objected to because of the following informalities:

The abstract of the disclosure does not commence on a separate sheet in accordance with 37 CFR 1.52(b)(4). A new abstract of the disclosure is requested and must be presented on a separate sheet, apart from any other text.

Claim Objections

Claims 1-5, 8-13, 16-19 are objected to because of the following informalities:

In claim 1, line 6, ")" should be deleted after alkyl,

In claim 5, line 3, "triinethyl" should be spelt trimethyl,

In claim 8, line 2, "(1R, 28, 4R)" should be (1R, 2S,4R),

In claim 8, line 2, "(+2" should be (-),

In claim 8, line 4, "-342-" should be "-3-[2-",

In claim 9, line 6, "dirnethyl" should be spelt trimethyl,

In claim 14, line 3, "(+27" should be (-)-2-,

appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 4, 13, 19, 20-21 are rejected under 35 U.S.C. 112, second paragraph, as being vague for failing to particularly point out and distinctly claim the subject matter which the applicant regards as the invention. It is not clear if the recitation "ALS" is part of the claim. If it is intended to be part of the claim as a limitation, it cannot be enclosed in the parenthesis.

Claims 4, 13, 19, 20-21 are further rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 4, 13, 19, 20-21 contain the abbreviation ALS. Where an abbreviation name is used in a claim as a limitation, the claim does not comply with the requirement of 35 U.S.C. 112, second paragraph. The claim scope is uncertain since the abbreviation cannot be used properly to identify the disorder, accordingly, the claims are vague, and indefinite.

Claims 2, 11, 17, 20, 21, 22 are further rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since

the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claims 2, 11, 17, 20, 21, recites the broad recitation “acute ischemic or traumatic brain and spinal damages”, and the claims also recites “especially the various types of stroke or cerebral vasospasm, severe brain vessel occlusion, neuronal loss” which is the narrower statement of the range/limitation; claim 22, recites the broad recitation “compound of the general Formula I or a pharmaceutically acceptable acid addition salt thereof”, and the claim also recites “preferably (1R,2S,4R)-(-)-2- (2-dimethylaminoethoxy)-2-phenyl-1, 7, 7-trimethylbicyclo[2.2.1]heptane of the Formula II or a pharmaceutically acceptable acid addition salt thereof” which is the narrower statement of the limitation .

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-9, and 16-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-9, and 16-21 are rejected, as they provide the use of the compounds of claim 1 in the preparation of pharmaceutical compositions, but, since the claims does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced. It is unclear what applicant intends by the word "use" as to whether the claims are product or process claims.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-9, and 16-21 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claims 1-9, 16-21 are treated as pharmaceutical composition claims, and the following rejections are made.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-22 are rejected under 35 U.S.C. 102(b) as being anticipated by Maki-Ikola (WO 02/43726, PTO-1449).

Maki-Ikola discloses 1,7,7-trimethylbicyclo[2.2.1]heptane derivatives such as (1R,2S,4R)-(-)-2-phenyl 2-(dimethylaminoethoxy)-1,7,7-trimethyl-bicyclo[2.2.1]heptane, known as deramciclane and (1R,2S,4R)-(-)-2-phenyl 2-(methylaminoethoxy)-1,7,7-trimethyl-bicyclo[2.2.1]heptane, known as desmethylderamciclane or pharmaceutically acceptable salts thereof which include fumaric acid salt, which are same as instant compounds of Formula I. Maki-Ikola discloses pharmaceutical compositions comprising (1R,2S,4R)-(-)-2-phenyl 2-(dimethylaminoethoxy)-1,7,7-trimethyl-bicyclo[2.2.1]heptane or (1R,2S,4R)-(-)-2-phenyl 2-(methylaminoethoxy)-1,7,7-trimethyl-bicyclo[2.2.1]heptane in pharmaceutically acceptable excipients such as starch, lactose etc. See abstract; page 1; page 2; page 3. Administration of compositions comprising 1,7,7-trimethyybicyclo[2.2.1]heptane derivatives therein in an amount of about 5-150 mg/day in treating cognitive impairment in a mammal which includes dementia, Alzheimer's,

Parkinson' disease, a neurodegenerative disease is also taught i.e a neuroprotective method is disclosed. See abstract; page 8, claims.

Regarding the recitation "suitable for" the therapeutic indications defined in claims 2, 4, 11-13, do not impart any limitations to the scope of the claim, as any composition comprising a compound of formula I is to be considered as suitable for the treatment of diseases defined in claims 2, 4, 11-13.

Further, it is pointed out that the intended use of a product or composition do not further limit the claim because the recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See In re Casey, 152 USPQ 235 (CCPA 1967) and In re Otto, 136 USPQ 458, 459 (CCPA 1963).

Thus, Maki-Ikola anticipates instant claims 1-22.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-9, 16-21 are treated as composition claims, and the following rejections are made.

Claims 1-22 are rejected under 35 U.S.C. 102(b) as being anticipated by Istvan et al. (WO 03/007926, PTO-1449).

Istvan et al. discloses (1R,2S,4R)-(-)-2-(2-dimethylaminoethoxy)-2-phenyl-1,7,7-trimethyybicyclo[2.2.1]heptane derivatives such as (1R,2S,4R)-(-)-2-(2-dimethylaminoethoxy)-2-phenyl-1,7,7-trimethyybicyclo[2.2.1]heptane, known as deramciclane or pharmaceutically acceptable salts thereof such as deramciclane-fumarate which are same as instant compounds of Formula I, and pharmaceutical compositions comprising 1,7,7-trimethyybicyclo[2.2.1]heptane derivatives in pharmaceutically acceptable carriers. See abstract; page 1; pages 4-6; page 12, EXAMPLE 2, wherein a pharmaceutical compositions comprising 1,7,7-trimethyybicyclo[2.2.1]heptane-fumarate is disclosed; pages 14-16. Administration of the compositions therein in treating cognition enhancement in a mammal which includes mental disability consequent to stroke, dementia, Alzheimer's disease, Parkinson' disease, a neurodegenerative disease is also taught i.e a neuroprotective method is disclosed. See pages 14-17, claims.

Regarding the recitation "suitable for" the therapeutic indications defined in claims 2, 4, 11-13 do not impart any limitations to the scope of the claim, as any composition comprising a compound of formula I is to be considered as suitable for the treatment of diseases defined in claims 2, 4, 11-13.

It is pointed out that the intended use of a product or composition do not further limit the claim because the recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See In re Casey, 152 USPQ 235 (CCPA 1967) and In re Otto, 136 USPQ 458, 459 (CCPA 1963).

Thus, Istvan et al. anticipates instant claims 1-22.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-21 are rejected under 35 U.S.C. 102(b) as being anticipated by Gyula et al. (EP 1 052 245, PTO-1449).

Gyula et al. discloses (1R,2S,4R)-(-)-2-phenyl 2-(dimethylaminoethoxy)-1,7,7-trimethyl-bicyclo[2.2.1]heptane, known as deramciclane or pharmaceutically acceptable salts thereof which include fumaric acid salt, which are same as instant compounds of Formula I. See abstract; pages 11-12, claims 1-2. Gyula et al. discloses pharmaceutical compositions comprising (1R,2S,4R)-(-)-2-phenyl 2-(dimethylaminoethoxy)-1,7,7-

trimethyl-bicyclo[2.2.1]heptane or (1R,2S,4R)-(-)-2-phenyl 2-(methylaminoethoxy)-1,7,7-trimethyl-bicyclo[2.2.1]heptane in pharmaceutically acceptable excipients such as starch, lactose etc. See abstract; page 8, paragraphs [0041]-[0044]. It is disclosed that the compounds therein are useful as anxiolytic medicaments.

Regarding the recitation "suitable for" the therapeutic indications defined in claims 2, 4, 11-13 do not impart any limitations to the scope of the claim, as any composition comprising a compound of formula I is to be considered as suitable for the treatment of diseases defined in claims 2, 4, 11-13.

The intended use of a product or composition do not further limit the claim because the recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See In re Casey, 152 USPQ 235 (CCPA 1967) and In re Otto, 136 USPQ 458, 459 (CCPA 1963).

Thus, Gyula et al. anticipates instant claims 1-21.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA

1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-22 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-13 of copending Application No. 10/592462. Although the conflicting claims are not identical, they are not patentably distinct from each other because the subject matter embraced in the instant claims, pharmaceutical composition comprising (1R,2S,4R)-(-)-2-phenyl 2-(dimethylaminoethoxy)-1,7,7-trimethyl-bicyclo[2.2.1]heptane (deramciclane) or pharmaceutically acceptable salts thereof overlaps with the stated claims of US Application No 10/592462. The claimed composition is within the scope of the claims of the US Application No. 10/592462. It would have been obvious to a person of ordinary skill in the art at the time of invention to the instant particular pharmaceutical compositions comprising deramciclane or pharmaceutically acceptable salts thereof because '462 teaches such compositions. Therefore, the instant claims 1-22 are seen to be obvious over claims 1-13 of copending Application No. 10/592462.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-22 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-11 of copending Application No. 10/592461. Although the conflicting claims are not identical, they are not patentably distinct from each other because the subject matter embraced in the instant claims, pharmaceutical composition comprising deramciclane or pharmaceutically acceptable salts thereof overlaps with the stated claims of US Application No 10/592461. The claimed composition is within the scope of the claims of the US Application No. 10/592461. It would have been obvious to a person of ordinary skill in the art at the time of invention to the instant particular pharmaceutical compositions comprising deramciclane or pharmaceutically acceptable salts thereof because '462 teaches such compositions. Therefore, the instant claims 1-22 are seen to be obvious over claims 1-11 of copending Application No. 10/592461.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-22 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-25 of US Patent No. 5,652,270. Although the conflicting claims are not identical, they are not patentably distinct from each other because the subject matter embraced in the instant claims, pharmaceutical composition comprising deramciclane or pharmaceutically acceptable salts thereof overlaps with the stated claims of US Patent No. 5,652,270. The claimed composition is within the scope of the claims of the US Patent No. 5,652,270. It would have been obvious to a person

of ordinary skill in the art at the time of invention to the instant particular pharmaceutical compositions comprising deramciclane or pharmaceutically acceptable salts thereof because '270 teaches such compositions. Therefore, the instant claims 1-22 are seen to be obvious over claims 1-25 of US Patent No. 5,652,270.

Claims 1-22 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-14 of US Patent No. 6,093,747. Although the conflicting claims are not identical, they are not patentably distinct from each other because the subject matter embraced in the instant claims, pharmaceutical composition comprising deramciclane or pharmaceutically acceptable salts thereof overlaps with the stated claims of US Patent No. 6,093,747. The claimed composition is within the scope of the claims of the US Patent No. 6,093,747. It would have been obvious to a person of ordinary skill in the art at the time of invention to the instant particular pharmaceutical compositions comprising deramciclane or pharmaceutically acceptable salts thereof because '747 teaches such compositions. Therefore, the instant claims 1-22 are seen to be obvious over claims 1-14 of US Patent No. 6,093,747.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shobha Kantamneni whose telephone number is 571-272-2930. The examiner can normally be reached on Monday-Friday, 7.30 am-3.30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, Ph.D can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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